## Remarks

Claims 1, 19-21, 30-34, 36, and 39-48 are pending in the application. Claims 22, 24 and 27-29 have been cancelled by the present amendment, without prejudice to the filing of one or more continuing applications. Claims 1, 19-21, 30-33 and 42-48 have been withdrawn from consideration pursuant to a restriction requirement. Claims 34, 36 and 39-41 are under consideration and stand rejected.

Reconsideration is requested in view of the above changes, the following remarks and the accompanying Declaration of Professor Arne Miller Under 37 C.F.R. 1.132 ("Miller Decl."). Professor Miller is an expert in the field of radiation processing, including modification of materials by radiation processing, with 41 years experience in the field. His accomplishments include operating the High Dose Radiation Laboratory at the Riso DTU, Technical University of Denmark, and being Editor-in-Chief for the journal *Radiation Physics and Chemistry* (Elsevier).

Response to 35 USC §102 Rejection of Claims 22, 24 and 27-29

Claims 22, 24 and 27-29 have been rejected as being allegedly anticipated by Shalaby. The rejection is moot in view of the cancellation of these claims.

Response to 35 USC §102 Rejection of Claims 34, 36 and 39-41

Claims 34, 36 and 39-41 have been rejected as being allegedly anticipated by Shalaby. The rejection alleges that Shalaby teaches an absorbable medical device, such as a suture, that is irradiated with an electron beam. The rejection alleges that since the outer surface of the objects irradiated by Shalaby receive more radiation, the outer surface would have a lower molecular weight than the inner core of the object.

Even assuming *arguendo* that a gradient could be created using the teachings of Shalaby, which applicant contends would not happen, such a gradient would not run from the *entire* outer surface to the core, as is required by the present claims. It is inherent from Shalaby that any gradient would run from the outer surface of the article proximate to the source of radiation, to the outer surface distal to the source of radiation. There is no disclosure in Shalaby of moving

the surface of the suture relative to the radiation source. It is clear, therefore, that the radiation would be applied to the suture from a fixed angle. This could not result in an article in which the *entire* outer surface of the article has been irradiated to a higher level (and thus having its mass distribution reduced/bioabsorbability increased), as the core would actually receive a higher radiation dose than the distal surface. Such a gradient would not be within the ambit of the present clams. Furthermore, such a gradient would not be desirable as it would not allow for the controlled bioabsorption of the article from the outer surface toward the core.

Figure 1, below, shows conventional electron beam sterilization, as would be allegedly employed by Shalaby. The object to be sterilized is moved on a conveyor belt through an electron beam with a suitable penetration energy in relation to the device dimensions and material such that a suitable dose of radiation, which can penetrate the device in a short time.

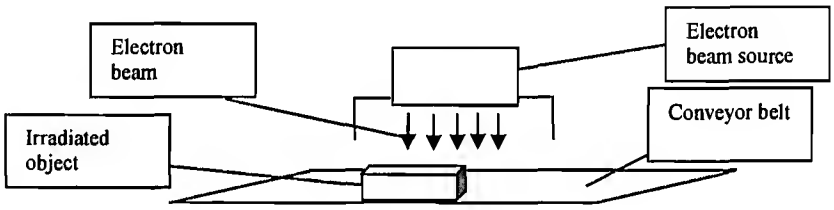



Figure 1

Examiner acknowledges that there is no explicit disclosure in Shalaby of rotating or moving a suture to be sterilized in relation to an electron beam source. Nevertheless, the Examiner alleges that this element is somehow present in Shalaby because "there is no disclosure that this does not happen". Examiner is respectfully reminded that to anticipate a claim under 35 U.S.C. § 102, a single prior art reference must disclose each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the invention in the possession of the public. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). The prior art reference must disclose, either expressly or under the principles of inherency, every limitation of the claim in issue. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1255- 56 (Fed. Cir. 1989). *Kalman*

*v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). *Verdegaal Bros. v. Union Oil Co. Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

As Examiner acknowledges that there is no *explicit* teaching in Shalaby for rotating a suture to be sterilized in an electron beam source, then pursuant to the above authorities, the missing element must be inherent in the teaching of Shalaby. But Examiner has failed to establish *prima facie* that the element in question is inherently present.

When relying on an inherency theory, the Office must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. MPEP 2112 and *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int.1990). The Office first must establish a reason to believe that the element, in fact, is an inherent characteristic of the prior art. *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). Only then does the Office possess the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the allegedly inherent characteristic. *In re Swinehart*, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 229 (C.C.P.A. 1971). It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1601* (Fed. Cir. 2002). As the CCPA stated in *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939)) (internal citations omitted): "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

The fact that Shalaby does not explicitly disavow suture rotation relative to an electron beam source falls far short of demonstrating that such a rotation "necessarily flows" from Shalaby. Far more is required to establish the inherency of that missing element in Shalaby. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). In *Rijckaert,* a rejection for inherent anticipation was reversed because it was based on what *would* result due to optimization of conditions, not what was necessarily present in the prior art. Similarly, as here, the missing element of suture rotation relative to an e-beam source would be present in the practice of Shalaby only if the skilled

artisan made a conscious effort to do so; there is no disclosure whatsoever in the four corners of the Shalaby document that would provide such inducement. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

It is respectfully submitted that the rejection fails to establish a *prima facie* case for anticipation by inherency. As such, the burden has not shifted to applicant to prove otherwise. *See In re Best, supra*; *In re Swinehart, supra*. Notwithstanding, the following remarks are provided, in the alternative.

Multisided irradiation or rotation of the device in front of the radiation beam is not mentioned by Shalaby. Based on the absence of any such a teaching, in order for a device to be sterilized, penetrating radiation must therefore be used, *i.e.*, the skilled artisan would understand that an electron beam would be used in the method of Shalaby that would fully penetrate the medical device. Miller Decl. ¶3.3-3.4. This would be in accordance with conventional techniques used to sterilize medical devices such as sutures using an e-beam, and is as suggested by the Shalaby examples which relate to a suture and the use of gamma radiation. Miller Decl. ¶3.4.

There is no teaching in Shalaby, either expressly or inherently, of a substrate having a molecular weight distribution that changes from the outer surface to the core such that average molecular weight at the core is greater than at the entire outer surface. Quite the contrary, Shalaby would be understood by a person skilled in the art as aiming to maintain homogeneity of physical properties in an irradiated device. While Shalaby is directed "modulating the physical properties of absorbable, ester-based polymer" (paragraph [0005]), the skilled artisan would understand "modulating" to mean "changing"; but "changing" does not mean creation of gradients. Miller Decl. ¶3.5. There is no mention in Shalaby of the generation of change gradients. *Id.* The skilled artisan would understand that "modulating" means modulation of homogeneous physical properties. *Id.* Also, while Shalaby mentions "the mass loss breaking strength retention profiles" (paragraph [0005]), the skilled artisan would understand these profiles to be modulation as a function of a homogeneous dose of radiation. *Id.*

Yet other teachings of Shalaby indicate that it is directed to maintaining homogeneity of physical properties in an irradiated device, not the creation of gradients. Shalaby is concerned with modulating the breaking strength of a medical device such as a suture, to allow an assessment of breaking strength to be made more easily (paragraph [0010]). Miller Decl. ¶3.6. Accordingly, a uniform degradation of the polymer across the thickness of the medical device would be sought. *Id.* This contrasts the claimed molecular weight distribution of the present invention which changes gradually from the outer surface to the core wherein the average molecular weight at the core is greater than the entire outer surface.

Shalaby also discusses the use of the dose modulation of high radiation energy to shorten the time frame required for absorbable devices to undergo practically complete adsorption at the implant site (paragraph [0010] of Shalaby). Miller Decl. ¶3.7. There is no discussion or suggestion provided by Shalaby of a different molecular weight distribution across the thickness of the device. *Id.* This emphasizes that Shalaby is concerned with a uniform degradation of the polymer across the thickness of a medical device. *Id.* Shalaby would not be understood by the skilled artisan to create a molecular weight gradation in a medical device.

Accordingly, one of ordinary skill in the art would consider Shalaby as providing no teaching or suggestion of an implantable substrate having a molecular weight distribution that changes gradually from the outer surface to the core such that average molecular weight at the core is greater than at the entire outer surface. Miller Decl. ¶3.8. The skilled artisan would not expect Shalaby's method for sterilizing and modulating the physical properties of a medical device would result in an implantable substrate with such a molecular weight distribution, wherein the rate of bioabsorbability of the device core is less than the rate of bioabsorbability of the device surface. Miller Decl. ¶3.9.

Even assuming *arguendo* that a molecular weight gradient would be created by following the teachings of Shalaby, which is not the case, any such gradient would run from the outer surface of the object proximate to the source of radiation (region of highest radiation), to the outer surface distal to the source of radiation (region of lowest radiation), as illustrated by Fig. 2:

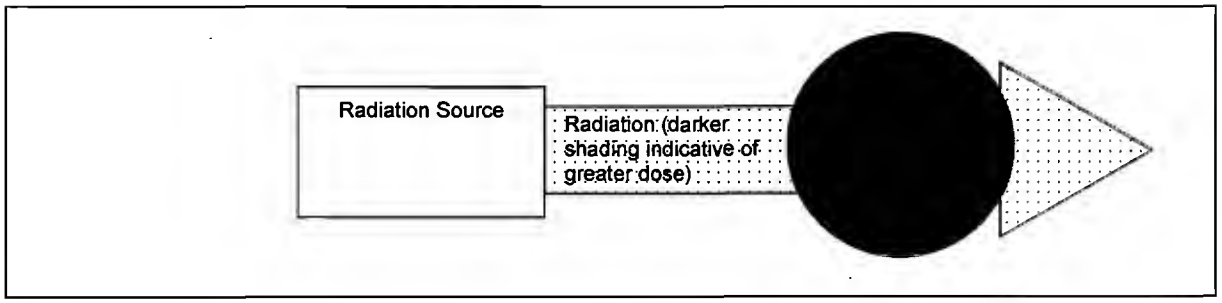



Figure 2

Claim 34 requires that "the average molecular weight at the core is greater than the average molecular weight at the *entire outer surface*" of the irradiated object. Shalaby would only provide the result in Fig. 2, wherein the shading is inversely proportional to the molecular weight. Clearly, it cannot be said that the average molecular weight would be greater at the core than the *entire* surface. The surface distal to the electron beam source would not have a molecular weight lower than the core, as shown in Fig. 2.

The radiation dose as provided to an object according to the present invention is represented by Figure 3. The shading, representing the radiation dose, is inversely proportional to the average molecular weight. All regions of the surface have a molecular weight that is lower that the molecular weight at the core .

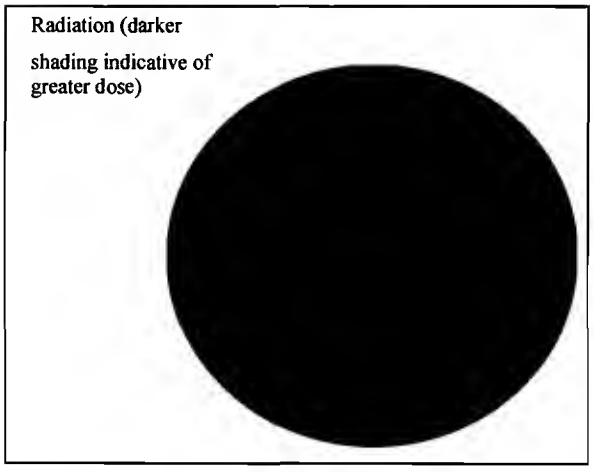



Figure 3

The articles (sutures and adhesive) of Shalaby do not inherently comprise a gradient in the orientation as required by the present claims.

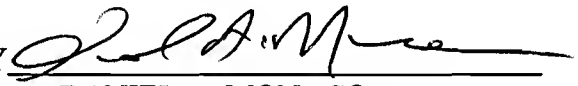
The bioabsorbable, implantable substrate of claim 34 is novel and nonobvious over Shalaby. Claim 34, and its dependent claims 36 and 39-41 are allowable for Shalaby.

Conclusion

The claims remaining in the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

FRASER JAMES BUCHANAN

BY 

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